Response to Comments of the Examiner

Claims 5-11 have been rejected under 35 U.S.C 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter wich applicant regards as the invention. The rejection is respectfully traversed. In fact, what is measured ins binding activity. That is the function of the test. That it has use for detecting salt sensitivity is a use that is particularly taught. Not everything that is taught in an application as being the ultimate objective is not required to be stated in a claim. Otherwise, all chemical claims and all method claims would be required to state a particular use. The method is for testing binding, as identified in the claim. The applicant would urge that the art knows how to measure radioactivity as recited in the claims. The steps of preparation of samples along with the recitation of measurement of radioactivity (a widely used method is recited at the last sentence of page 6) would clearly be understood as standard terminology in the art. The steps of preparation of the samples along with the teaching of a means (scintillation) of measuring the radioactivity, a common procedure, would be clearly understood by one of ordinary skill in the art, for which the claims are written. Furthermore, since the specification clearly teaches how to measure the biding activity being measured, the claims could clearly be understood in light of the description. Hence, it is urged that one of ordinary skill in the art would clearly know what is being measured and how it is being measured.

Responding to the examiners statement that is unclear why the samples are split, the applicant would state the reason for two sets of samples in the method of U.S. patent application 10/617,254 is that one set serves as background for the other. Binding can be divided into two components, specific and non-specific. In the method of the patent application, the binding that is measured when radiolabeled 25-hydroxyvitamin D (25-OHD) is incubated with a urine sample is total binding (set 2). The addition of 200-fold unlabeled 25-OHD to the samples of set 1 allows for the unlabeled 25-OHD to successfully compete against the radiolabeled 25-OHD and prevent its binding to specific vitamin D binding proteins in the urine sample. The value obtained for set 1 samples is, however, generally greater than zero and is defined as non-specific binding. For a given urine sample, the average of the set 1 duplicates (non-specific

binding) is subtracted from the average of the set 2 duplicates (total binding) to obtain specific binding.

Regarding use of terminology, the examiner states: "Applicant sometimes uses the designation "vitamin D" and sometimes "vitamin D_3" seemingly interchangeably and it is unclear what is desired." " Vitamin D_3" is used to refer to a specific compound used in the assay as a reagent and "vitamin D" is used when speaking in general. The reagent used is the vitamin D_3.

The examiner then rejects claims 5, 9 and 11 under 35 U.S.C. 103(a) as unpatentalbe over DeLuca, et al. and Norman in view of Garman, Blume and Cook. The rejection is respectfully traversed. Claim 5, reciting a kit containing radiolabeled 25-hydroxyvitamin D_3, unlabeled 25-hydroxyvitamin D_3 and instruction for measurement of vitamin D binding proteins and dependent claims 9 and 11 have been rejected over DeLucia '777 and Norman '150. The rejection has been traversed by the applicant. DeLucia disclosed and claims only methods for making a group of radiolabeled vitamin D compounds and intermediates produced in the methods disclosed therein. There is no teaching therein, nor motivation, to suggest preparation of a kit for any purpose having the components recited in the claims. Though the examiner has urged it would be obvious to make such a kit, it has been impossible to determine where the examiner finds, in that reference, a motivation or suggestion to make such a product. If such motivation or suggestion is found, enlightenment as to where would be appreciated.

Norman does not provide any additional motivation or teaching that would, with DeLucia, suggest or motivate one to make the kit of the invention. Norman simply teaches a method for making the metabolites of 25-hydroxycholecalciferol using mitochondrial preparations. The question is, does the recitation of one prior art ingredient recited in the claim, said ingredient being, in the prior art, in a culture to make metabolites of the ingredient, suggest a kit containing one of the ingredients as a component for a kit for any purpose? No enlightenment as to how such recitation renders the claimed invention obvious has been provided by the examiner. It is urged by the applicant that the mere recitation of (1) a component of a kit in one prior art reference teaching how to make that component and the recitation of another component (2) recited in the claim as taught in the second prior art reference as an ingredient in a cell culture does not render a kit containing components (1) and (2) obvious for any reason or purpose. Hence, the rejection can not stand.

The examiner cites case law related to the combination of known elements. However, it should be noted that there is no reference requiring all of the elements required in the claims, and there is no motivation to combine all of the required elements of the claims for any reason. It is respectfully urged that the examiner explain more clearly what would constitute motiviation for such a combination. In short, the examiner has failed to show an "existing product" having all of the claimed elements.

It is respectfully requested that claims 6, 7, 8 and 10 be deemed to comply with the requirements of U.S.C. 112 second paragraph as to particularly pointing out and distinctly claiming the subject matter the applicant regards as the invention.

It is also requested that claims 5, 9 and 11 be deemed allowably under 35 U.S.C. 103 as unobvious over DeLucia, et al. and Norman, et al.

Respectfully submitted,

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